AUG 1 2 2004

Page ① of ④

5. 510(K) SUMMARY

DISPOSABLE

SHINMED various models of Electro-Surgical Pencils,

Models: SW12200, SW12202, SW12300

510K: K033027

Submitted by:	SHINING WORLD HEALTH CARE CO., LTD. 6F, No.8, Lane 7, Wu-Chun Road, Wu-Ku Industrial Park, Taipei, China (Taiwan)
Contact person:	Dr. Jen, Ke-Min No.58, Fu-Chiun Street, Hsin-Chu City,Taiwan, ROC Tel: 886-3-5208829 fax: 886-3-5209783 E-mail: ceirs.jen@msa.hinet.net
Date Summary Prepared:	September 20, 2003
Name of the Device:	Device , Electrosurgical, Cutting & Coagulation & Accessories
Proprietary Name:	SHINMED various models of electro-surgical pencils
Models:	SW12200, SW12202, SW12300
Predicate Device:	*Gyrus PlasmaKinetic Superpulse System (Generator & Accessories)* *510K No – K031085*

Statement of Intended Use: The Shinmed Various Models of Electro-Surgical Pencils. SW12200, SW12202, SW12300 used with a 510K-clearance generator is intended for use for ablation, removal, resection and coagulation of soft tissue and where associated hemostasis is required in open, endoscopic and laparoscopic surgical procedures.

The device is intended for use by qualified medical personnel trained in the use of electrosurgical equipment.

Comparison to Predicate Devices: The Shinmed Various Model of Electro-Surgical Pencil, SW12200, SW12202, SW12300, have been carefully compared to legally marketed devices with respect to intended use and technological characteristics. In addition, performance testing has been done to validate the performance of the device. The comparison and validation results presented in this 510k notification to the FDA show that the subject device is substantially equivalent to predicated device and is safe and effective in its intended use.

5. 510(K) SUMMARY

SHINMED various models of reusable Electro-Surgical Pencils,
Models: SW11100, SW11200, SW11202, SW11300

510K: K033027

Submitted by:	SHINING WORLD HEALTH CARE CO., LTD. 6F, No 8, Lane 7, Wu-Chun Road, Wu-Ku Industrial Park, Taipei, China (Taiwan)
Contact person:	Dr. Jen, Ke-Min No.58, Fu-Chiun Street, Hsin-Chu City,Taiwan, ROC Tel: 886-3-5208829 Fax: 886-3-5209783 E-mail ceirs.jen@msa.hinet.net

Date Summary Prepared:	September 26, 2003
Name of the Device:	Device , Electrosurgical, Cutting & Coagulation & Accessories
Proprietary Name:	SHINMED various models of reusable electro-surgical pencils
Models:	SW11100, SW11200, SW11202, SW11300
Predicate Device:	*Gyrus PlasmaKinetic Superpulse System (Generator & Accessories)* *510K No – K031085*

Statement of Intended Use: The Shinmed Various Models of reusable Electro-Surgical Pencils, SW11100, SW11200, SW11202, SW11300 used with a 510K-clearance generator is intended for use for ablation, removal, resection and coagulation of soft tissue and where associated hemostasis is required in open, endoscopic and laparoscopic surgical procedures.

The device is intended for use by qualified medical personnel trained in the use of electrosurgical equipment.

Comparison to Predicate Devices: The Shinmed Various Model of reusable Electro-Surgical Pencil, SW11100, SW11200, SW11202, SW11300 have been carefully compared to legally marketed devices with respect to intended use and technological characteristics. In addition, performance testing has been done to validate the performance of the device. The comparison and validation results presented in this 510k notification to the FDA show that the subject device is substantially equivalent to predicated device and is safe and effective in its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 1 2 2004

Dr. Ke-Min Jen
Shining World Health Care Co., LTD.
No. 58, Fu-Chiun Street
Hsin-Chu City, Taiwan, ROC

Re: K033027
Trade/Device Name: SHINMED Various Disposable Models of Electro-Surgical Pencils, SW12200, SW12202, SW12300, SW11100, SW11200, SW11202, SW11300
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: July 14, 2004
Received: July 22, 2004

Dear Dr. Jen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Miriam C. Provost

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

4. INDICATIONS FOR USE STATEMENT

Applicant Shining World Health Care Co., Ltd

510(k) Number : ~~TO BE ASSIGNED~~ K033027

Device Name : SHINMED Various Models of Electro-Surgical DISPOSABLE Pencils, SW12200, SW12202, SW12300

Indications for Use :

- *The Shinmed Various Models of Electro-Surgical Pencils, SW12200, SW12202, SW12300 used with a 510k-clearance generator are intended for use for ablation, removal, resection and coagulation of soft tissue and where associated hemostasis is required in open, endoscopic and laparoscopic surgical procedures.*
- *The device is intended for use by qualified medical personnel trained in the use of electrosurgical equipment.*

Prescription Use ✓ OR Over-The-Counter ____

Per 21 CFR 801.109 (Optional Format 1-2-96)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH Office of Device Evaluation (ODE)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K033027

4. INDICATIONS FOR USE STATEMENT

Applicant : SHINING World Health Care Co., Ltd.

510(k) Number : K 033027

Device Name : SHINMED electrosurgical pencils, reusable models: (SW11100, SW11200, SW11202, SW11300); disposable models: (SW12200, SW12202, SW12300)

Indications for Use :

- *The SHINMED Various Models of Electro-Surgical Pencils used with a 510k-clearance generator are intended for use for ablation, removal, resection and coagulation of soft tissue and where associated hemostasis is required in open, endoscopic and laparoscopic surgical procedures.*
- *The device is intended for use by qualified medical personnel trained in the use of electrosurgical equipment.*

Prescription Use √ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Miriam C. Provost

(Division Sign-Off)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of General, Restorative, and Neurological Devices

510(k) Number K 033027